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MAILED

APR 5 - 2000

PAT. & T.M. OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

Applicants: TABAKOFF
Application No.: 09/171,697
Filed: 10/23/98
For: COMPOUNDS, COMPOSITIONS AND METHOD
SUITABLE FOR AMELIORATION OF WITHDRAWAL
SYNDROMES AND WITHDRAWAL-INDUCED BRAIN
DAMAGE

The above-identified application or patent has been forwarded to the Board of Patent Appeals and Interferences because it is adjudged to interfere with another application or patent. An interference has been declared. The interference is designated as No. 104,522.

Notice is hereby given the parties of the requirement of the law for filing in the Patent and Trademark Office a copy of any agreement "in connection with or in contemplation of the termination of the interference." 35 U.S.C. § 135(c).

mcK

FRED E. MCKELVEY
Senior Administrative Patent Judge

The opinion in support of the decision being entered today is not binding precedent of the Board.

Paper 1

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MAILED

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

APR 5 - 2000

PAT. & T.M. OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

ALFRED C. NICHOLS and K. LEMONE YIELDING,

Junior Party,
(Patent 5,783,700),

v.

BORIS TABAKOFF, LAWRENCE SNELL
and PAULA L. HOFFMAN,

Senior Party
(Application 09/171,697).

Patent Interference No. 104,522

NOTICE DECLARING INTERFERENCE
(37 CFR § 1.611)

An interference is declared (35 U.S.C. § 135(a)) between the above-identified parties. Details of the application(s), patent (if any), reissue application (if any), count(s) and claims designated as corresponding or as not corresponding to the count(s) appear in an "Attachment" to this NOTICE DECLARING INTERFERENCE.

1. Judge designated to handle the interference

Senior Administrative Patent Judge Fred E. McKelvey has been designated to handle the interference. 37 CFR § 1.610.

2. Telephone calls to the board

Telephone calls to the board regarding this interference shall be placed to 703-308-9797.

Telephone calls in which counsel wish an administrative patent judge to participate shall be inter partes in which at least one counsel for each party and the administrative patent judge designated to handle this interference shall participate. There are no exceptions. Any attempt to initiate an ex parte telephone call, e-mail or other form of communication to an administrative patent judge in connection with this interference may result in sanctions (37 CFR § 1.616; 35 U.S.C. § 32; 37 CFR § 10.23(b)(5); 37 CFR § 10.93). Attention is directed to (1) an opinion in Interference 104,AAA (Bd. Pat. App. & Int. December 2, 1998) (Paper 10) and (2) an opinion in Interferences 104,BBB and 104,CCC (Bd. Pat. App. & Int. December 23, 1998) (Paper 4); both of which are on the PTO Web Page at:

<http://www.uspto.gov/web/offices/dcom/bpai/its.htm>.

No attempt shall be made to contact any administrative patent judge not designated to handle this interference without prior permission of an interference administrator (703-308-9797) or the administrative patent judge designated to handle this interference.

Telephone calls requesting a telephone conference call or information of a procedural nature shall be placed to an interference administrator, a paralegal or a legal technician, assigned to the Trial Section of the Interference Division of the board. The Trial Section is to handle interlocutory matters in interferences. A party seeking a conference call with an administrative patent judge should be prepared to advise the interference administrator, paralegal or legal technician why a conference call is believed to be needed.

3. Filing papers with the board

Certificates of service and transmittal sheets

Proof of service must accompany all papers filed in an interference. 37 CFR § 1.646(e). Each paper filed in the interference shall have its own certificate of service, which shall appear at the end of the paper;¹ a single certificate of service shall not be used for two or more separate papers.

The use of papers in the nature of a transmittal sheet is discouraged.²

How papers may be delivered to the board

The parties may file papers with the board as follows:

¹ The purpose for this requirement is to make it easier for the Office of the Clerk to verify that each paper in an interference has been served.

² The use of transmittal sheet listing documents being filed unduly complicates entry of papers into files and docketing of papers in the Office of the Clerk.

a. Hand-delivery to the Office of the Clerk between the hours of 8:30 a.m. and 5:00 p.m. at:

Board of Patent Appeals and Interferences
Crystal Gateway 2
10th Floor
1225 Jefferson-Davis Highway
Arlington, VA 22202.

Any paper hand-delivered to the Office of the Clerk before 10:00 a.m. is deemed to have been filed the previous business day provided the paper was properly served the previous business day.³

b. Commercial overnight delivery service, addressed as follows:

Board of Patent Appeals and Interferences
Crystal Gateway 2
10th Floor
1225 Jefferson-Davis Highway
Arlington, VA 22202.

Papers filed by a commercial overnight delivery service will be deemed filed on the date they are delivered to the commercial overnight delivery service.

c. Delivery to the PTO Mail Room or by U.S. Postal Service, including Express Mail, addressed as follows:

BOX INTERFERENCE
Commissioner of Patents and Trademarks
Washington, D.C. 20231.

³ The ability to file a paper in the Office of the Clerk by 10:00 a.m. is designed to eliminate any need to hand-deliver papers with the PTO Mail Room after business hours.

d. Facsimile (703-305-0942).

Papers exceeding five (5) pages in length cannot be filed by facsimile without prior permission of an interference administrator. Unless expressly ordered by the administrative patent judge, a subsequent confirmation copy is not needed when filing a paper by facsimile.

Hand-delivery to the Office of the Clerk of the Board will minimize the time it takes to (1) process the paper and (2) decide any request made in the paper.

4. Use of cover sheet in filing papers in interference cases with the board

The first page of all papers filed with the board in connection with this interference shall be pink similar to the pink first sheet accompanying this NOTICE DECLARING INTERFERENCE.

5. Requirement for filing two copies of each paper

When presenting a paper in this interference, each party is required to submit (1) an original and (2) one copy of each paper, the copy shall be marked at the top:

"COPY FOR JUDGE"

6. Notice under 35 U.S.C. § 135(c)

Notice is hereby given of the requirement of 35 U.S.C. § 135(c) for filing in the PTO a copy of any agreement "in connection with or in contemplation of the termination of the interference." See Unisys Corp. v. Commissioner of Patents and

Trademarks, 39 USPQ2d 1842 (D.D.C. 1993). The date an interference terminates is set out in 37 CFR § 1.661.

7. Lead and backup counsel

Within **fourteen (14)** days of the date of this NOTICE DECLARING INTERFERENCE, each party is required to identify in a separate paper

- a. a lead counsel (37 CFR § 1.613(a));
- b. a backup lead counsel;
- c. a mailing address;
- d. in the event the mailing address is a Post Office Box, an address where overnight packages may be delivered;
- e. telephone number;
- f. facsimile number and
- g. internet e-mail address, if available.

If lead counsel and/or backup counsel are not counsel of record (37 CFR § 1.34(b)) in the application or patent involved in this interference, then within **fourteen (14) days** of the date of this NOTICE DECLARING INTERFERENCE, an appropriate power of attorney shall be filed.

8. Real party in interest

Within **fourteen (14) days** of the date of this NOTICE DECLARING INTERFERENCE, each party shall notify the board in a separate paper of any and all right, title, and interest in any application or patent involved in the interference (37 CFR § 1.602(b)).

All parties are obligated to continually and promptly update changes of the real party in interest.

9. Request for copies of files

The parties to the interference have access to the patent and application files involved in the interference, as well as any benefit files identified in this order. 37 CFR § 1.612(a).

The parties are advised that the interference file does not include any involved application, patent or benefit files, all of which are maintained separate from the interference file.

Within **fourteen (14) days** of the date of this order, each party shall file **with the board** (not another office in the Patent and Trademark Office) a separate paper requesting copies of those files identified in this order which that party would like to obtain. The request must include:

- a. a list by patent number and application number of the files desired,
- b. a Patent and Trademark Office Deposit Account to which fees may be charged for making copies, and
- c. a complete street, city and state address (not a P.O. Box) of the location where copies are to be shipped.

The parties are encouraged to file requests for copies by facsimile.

Within **twenty-one (21) days** of the date of this notice, the board will forward all requests timely received and all necessary files to the Office of Public Records (OPR). An order will be

entered by the Trial Section notifying the parties that their respective orders have been forwarded to OPR. . OPR will make the copies, which will be shipped via overnight delivery service. ; OPR has advised the board that copies will be made and shipped within **fourteen (14) days** of receipt of the request and files.

The parties are further advised that during the pendency of the interference, the files may be inspected only at the Office of the Clerk of the Board and generally are unavailable while copies are being made at OPR.

The parties are still further advised that failure to timely request copies of files will almost never constitute a basis for granting an extension of time (37 CFR § 1.645(a)). Thus, an extension of time cannot be expected based on non-receipt of requested files where a party did not timely place an order for copies in the manner set out above.

10. Size of paper⁴

With the possible exception of original exhibits of a different size, all papers (e.g., identification of lead counsel, identification of real party in interest, motions, preliminary motions, preliminary statements, copies of deposition transcripts, briefs, etc.) filed in this interference shall be

- a. 8½ x 11 inch paper or
- b. A4.

⁴ The purpose of this requirement is to facilitate storage of papers, files and evidence at the board.

The board prefers use of 8½ x 11 inch paper. Papers of a different size (e.g., legal size) shall not be filed.

11. Holes at the top of papers⁵

All papers filed in this interference shall have two holes punched at the top spaced at 2-3/4 inches apart (each hole spaced equidistant from an imaginary center line running from the top to the bottom of the paper) so that the papers may be placed in interference files maintained by the PTO.

12. Prohibition against presenting duplicate papers⁶

When presenting a paper in this interference, a party shall not submit with the paper (as an appendix, exhibit, or otherwise) a copy of a paper previously filed in the interference (37 CFR § 1.618(b)).

13. Prohibition against incorporation by reference of arguments made in another paper⁷

Arguments presented in one paper shall not be incorporated by reference to another paper.

⁵ The purpose of this requirement is to facilitate placing papers in files and to avoid the need to unstaple papers, thereby minimizing the chance that a page of a particular paper will be misplaced.

⁶ The purpose of this requirement is to (1) minimize the size of files and (2) facilitate storage of material in the limited storage space available to the board.

⁷ The purpose of this requirement is to minimize the chance that an argument will be overlooked and to maximize the efficiency of the decision-making process.

14. Citation of case law in papers

When citing a decision of a court which is published in the West Reporter System and the USPQ, counsel should provide parallel citations, e.g., Aelony v. Arni, 547 F.2d 566, 192 USPQ 486 (CCPA 1977); In re Deckler, 977 F.2d 1449, 24 USPQ2d 1448 (Fed. Cir. 1992).

Binding precedent is the following:

- a. Decisions of the U.S. Supreme Court.
- b. Decisions of the Court of Appeals for the Federal Circuit, the former CCPA and the former Court of Claims. See South Corp. v. United States, 690 F.2d 1368, 1370-71, 215 USPQ 657, 657-58 (Fed. Cir. 1982) (en banc), and In re Gosteli, 872 F.2d 1008, 1011, 10 USPQ2d 1614, 1616-17 (Fed. Cir. 1989) (where there is a conflict between two or more decisions of the former CCPA, the later CCPA decision controls).
- c. Decisions of the Commissioner of Patents and Trademarks.
- d. Decisions of the Board of Patent Appeals and Interferences which have been determined to be binding precedent under the board's Standard Operating Procedure 2. See, e.g., Reitz v. Inoue, 39 USPQ2d 1838 (Bd. Pat. App. & Int. 1995).

Decisions of the regional courts of appeals and the district courts may be cited, but are not binding precedent.

Non-precedential decisions of federal courts shall not be cited.

Non-precedential decisions of the board may be cited, but are not binding.

The Manual of Patent Examining Procedure (MPEP) is a guide for patent examiners which is prepared by the Office of the Assistant Commissioner for Patents. The MPEP contains Chapter 2300 on interference practice. Generally, Chapter 2300 of the MPEP should not be cited in papers filed in this interference. Rather, counsel should instead cite only primary authority: the United States Code (USC), the Code of Federal Regulations (CFR), notices published in the Federal Register and/or Official Gazette, and binding precedent.

15. Copies of precedent relied upon

The parties are required to submit with the document in which a court opinion is cited a copy of any opinion which is not reported in West Publishing Company's Supreme Court Reporter, the F.2d, or the F.3d and the USPQ or USPQ2d.⁸

The parties are requested to submit with papers copies of court opinions and statutes for the convenience of board personnel--the copies of court opinions and statutes will not become part of the record.⁹

⁸ The reason for this requirement is that other court reporters are not readily available at the board.

⁹ The reason for this request is that administrative patent judges often work on cases out of the office where court reporters may not be readily available. If a particular opinion or statute is crucial to a position taken in a motion, opposition or reply, it may help expedite resolution of the motion if a copy of the opinion or statute accompanies the papers.

16. Service of papers by hand or Express Mail¹⁰

All papers served on opposing counsel in this interference shall be served by Express Mail (an overnight one-day delivery ; service of the U.S. Postal Service) (37 CFR § 1.646(d)); alternatively counsel may serve opposing counsel using any means which accomplishes an overnight one-day delivery, e.g., by hand, facsimile, or a commercial overnight delivery service.

The day a facsimile is transmitted, an overnight package is delivered to a courier or a paper is served by hand does not count in the calculating of the time for filing a response.

17. Conference call to set dates

A telephone conference call to set dates for action in this interference is scheduled for **2:30 p.m. (1430 hours Eastern Daylight Time) on 7 June 2000** (the call will be initiated from the PTO).

No later than **two business days** prior to the conference call, each party shall file and serve by facsimile a list of the preliminary motions the party intends to file.¹¹

¹⁰ The purpose of this requirement is to place all parties on a level playing field by avoiding different delivery times which inherently occur through the use of the U.S. Postal Service.

¹¹ The requirement for a list of preliminary motions attempts to improve the administration of justice, including reducing costs, by (1) helping the Trial Section and counsel arrive at an appropriate schedule for taking action during the preliminary motion phase of the interference, (2) permitting the Trial Section to determine that certain preliminary motions may be unnecessary and that other preliminary motions may be necessary and (3) revealing the possibility that there may be a dispositive preliminary motion. Submission of a list does not preclude the filing of additional preliminary motions not contained in the list. However, belated discovery of additional preliminary motions which a party believes may be necessary will not constitute a basis for enlarging the time for taking action in the preliminary motion phase.

A copy of a "sample" order setting times for taking action during the preliminary motion phase of the interference accompanies this NOTICE DECLARING INTERFERENCE. Counsel are encouraged to discuss the order by phone prior to the telephone conference call and to come to some mutual agreement as to dates for taking action.

18. Headings to be used on papers in the interference¹²

In papers filed with the board by party in this interference, the heading shown in the attached Appendix shall be used.

19. Copies of patents and literature mentioned in each specification (and translations, if available)¹³

Within **twenty-one (21) days** of a request by an opponent, a party:

a. shall serve on all opponents a legible copy of every requested patent, literature reference and test standard (e.g., an ASTM test), and in the case of patents, literature or test standards in a foreign language, a translation, if available, mentioned in the specification of the party's involved

¹² The purpose of this requirement is to standardize headings, to be able to immediately recognize which party is filing the paper and to facilitate calls by the staff of the board in the event correction is needed.

¹³ The purpose of the additional discovery authorized by this paragraph is to place the parties on a level playing field and to minimizing any difficulty with authenticating documents when a party would like to rely on a document cited in an opponent's specification. A party should have access to documents cited in its opponent's specification and it may be difficult for an opponent to locate those documents. 37 CFR § 1.687(c).

patent and/or application upon which the party will rely for benefit, and

b. shall file with the board a notice (without copies of the patents or literature) that it has served the patents and literature.

Upon a future request by the board, the parties should be prepared to promptly file copies of the patent, literature references and/or test standards.

20. Clean copy of claims¹⁴

Within **fourteen (14) days** of the date of this order, each party shall file **two (2) copies** of a clean set of all claims (as they exist as of the date of the declaration of this interference)

a. pending in the party's involved application or

b. contained in the party's involved patent

(including any changes which took place by way of a certificate of correction after granting of the patent and before declaration of the interference).

If the claims refer to a sequence, a copy of the sequence shall be included along with the clean copy of the claims.

¹⁴ The purpose of this requirement is to have readily available a clean copy of the claims of the parties. In applications, claims are often spread throughout the application file. In patents, there are often certificates of correction.

21. Application or patent with a drawing and/or claims containing means or step for performing a specified function limitations¹⁵

If any involved patent or application contains:

- (1) a drawing¹⁶ and/or
- (2) a claim designated as corresponding to a count reciting a means or step for performing a specified function (35 U.S.C. § 112, sixth paragraph),

then within **twenty-eight (28) days** of the date of this order, the party is required to file (in addition to the paper required by paragraph 20 of this order) a separate paper containing a copy of the claims in which:

- (a) following each element recited in each claim, the drawing numbers corresponding to that element are inserted in braces { }¹⁷ and in bold and
- (b) following each means or step for performing a specified function are inserted in braces { }, and in bold, all structure, material or acts described in the specification corresponding to that means or step (by references to the page(s) and line(s))

¹⁵ The purpose of this requirement is to allow all parties and the board to understand the precise scope of the claims which correspond to the count. Since a count may itself refer to a claim which contains a means or step for performing a specified function, the requirement will also make it easier to understand the scope of a count.

¹⁶ Where the drawing does not show the claimed invention (e.g., a graph plotting a property as a function of some condition, a table of data, etc.), then a paper is not required.

¹⁷ Braces { } are required instead of brackets [] because brackets are used in claims in reissue applications.

of the specification and/or figure and item number of the drawings).

An example follows:

An apparatus comprising

a pump { **Fig. 1, item 18** },

a body member { **Fig. 1, item 19** },

a first valve { **Fig. 2, item 25** },

means for calculating a numerical value for an exponent { **page 2, lines 8-10; page 4, lines 21-25; Fig. 2, item 34** },

means for printing { **page 5, line 8 through page 6, line 1; Fig. 3, items 45 and 46** }, and

a second valve { **Fig. 3, item 98** } ***.

If during the prosecution of the interference, a party presents (1) a new claim in an application which contains a drawing and/or (2) a new claim which recites a means or step for performing a specified function, the party shall (in addition to all other requirements of the rules) file a separate paper containing a copy of the new or amended claim complying with the requirements set out above.

If during the interference, a party files a preliminary motion seeking the benefit of an earlier application (1) containing a drawing or (2) with respect to a claim in an involved patent or application which recites a means or step for performing a specified function, the party shall (in addition to all other requirements of the rules) file an appendix to the

preliminary motion containing a copy of the claims complying with the requirements set out above.

If during the course of this interference, a party intends to argue that a structure, material or act is an equivalent (within the meaning of 35 U.S.C. § 112, sixth paragraph) of a structure, material or act described in the specification, then the party shall:

- a. promptly file a notice¹⁸ with the board of its intention to argue the equivalency;
- b. clearly set out the precise nature of the structure, material or act which is deemed to be equivalent to the structure, material or act described in the specification and
- c. bear the burden of proof of establishing the equivalency alleged.

22. Copy of papers in electronic and/or CD-ROM form¹⁹

At an appropriate time in the interference, and in addition to papers required to be filed by the rules or an order of the board, the parties are authorized to file either or both of (1) a

¹⁸ In the case of a preliminary motion, notice is deemed to be promptly given if it is given in the preliminary motion or, if raised by an opponent, in an opposition to a preliminary motion. In the case of priority, notice is deemed to be promptly given if a separate paper is filed with the board at the same time a party serves its case-in-chief. See Section D, ¶¶ 2 and 4 of the ORDER for TESTIMONY AND FILING OF THE RECORD and BRIEFING SCHEDULE.

¹⁹ The purpose of this paragraph is to put the parties on notice that they are authorized to file documents in electronic or CD-ROM form. Often documents in electronic or CD-ROM form (1) are more easily searched and (2) can minimize the chance that an argument or evidence will be overlooked by an administrative patent judge or other board personnel.

100mb ZIP® disk for a ZIP® disk drive and/or (2) a CD-ROM²⁰ (for use in an IBM compatible computer) containing any or all of the following documents:

- a. the specification,
- b. the claims,
- c. any motion, opposition or reply,
- d. affidavit²¹ testimony,
- e. exhibits,
- f. transcripts of cross-examination,
- g. principal, opposition and reply briefs at final hearing and
- h. other material, such as statutes, rules and court and administrative precedent relied upon in preliminary motions, principal briefs, oppositions and/or replies.

²⁰ Filing a CD-ROM would be subject to the following conditions:

1. The CD-ROM must be capable of operating on a computer with 486 or higher running on Windows 95 and Windows NT.
2. The board has monitor capability of 256 colors and an 800 x 600 screen setting.
3. The CD-ROM would have to be equipped with software that can be loaded onto the PTO computer and must be accompanied by instructions for its use.
4. Any party wishing to file the brief on CD-ROM must provide four (4) copies of the CD-ROM to the board.
5. One copy of the CD-ROM must be served on all opponents.
6. In addition, the required number of paper copies must also be filed in the PTO and served on all opponents.

²¹ Affidavit includes a declaration. 37 CFR § 1.601(b).

23. Time to respond to miscellaneous motions under 37 CFR § 1.635

There are three kinds of motions which can be filed in an interference:

- a. A preliminary motion under 37 CFR § 1.633.
- b. A motion to correct inventorship under 37 CFR § 1.634.
- c. A miscellaneous motion under 37 CFR § 1.635.

The time for filing an opposition to a miscellaneous motion under 37 CFR § 1.635 is hereby set to be **five (5) working days** after service of the motion. 37 CFR § 1.638(a).

The time for filing a reply to an opposition to a miscellaneous motion under 37 CFR § 1.635 is hereby set to be **three (3) working days** after service of the opposition. 37 CFR § 1.638(b).

A motion under 37 CFR § 1.635 may be denied prior to receipt of an opposition. A motion under 37 CFR § 1.635 may be granted after an opposition is filed and prior to receipt of a reply.

24. Requests under 37 CFR § 1.642 to add an application or patent

A request pursuant to 37 CFR § 1.642 to add an application or patent to an interference shall be made in the form of a miscellaneous motion under 37 CFR § 1.635. Any motion should:

- a. identify the additional application or patent to be added;

- b. certify that a complete copy of the file wrapper of application has been served on all opponents; and
- c. explain which claims of the patent or application should be designated as corresponding to the count.

25. Manner of styling papers²²

The style of all papers shall appear on a single line, shall be free of the words "et al".

All motions and preliminary motions shall be consecutively numbered starting with number 1.

Any opposition to a motion or preliminary motion shall bear the same number as the motion it opposes.

Any reply to an opposition shall bear the same number as the opposition to which it replies.

In connection with a motion or preliminary motion and in a second line, a party may specify the nature of the motion or preliminary motion. Examples of how papers, motions, preliminary motions, opposition and replies should be styled follows.

- a. Jones Designation of Lead Attorney
- b. Smith Designation of Real Party in Interest
- c. Jones Request for Copy of Files
- d. Smith Filing of Preliminary Statement
- e. Jones Service of References

²² The purpose of this requirement is to simplify docket entries at the board.

- f. Smith Clean Copy of Claims
- g. Jones Miscellaneous Motion 1
(for additional discovery)
- h. Jones Preliminary Motion 2
(for judgment based on prior art)
- i. Jones Preliminary Motion 3
(for judgment based on lack of enablement)
- j. Jones Motion to Correct Inventorship 4
- k. Smith opposition 2
(To Jones preliminary motion 2)
- l. Smith opposition 4
(To Jones motion to correct inventorship 4)
- m. Jones reply 2
(To Smith opposition 2)

26. Manner of presenting motions, oppositions and replies²³

Motions

- a. In presenting a motion, a party shall set out in the following order:
 - (1) The precise relief requested (two examples are (a) Jones moves to be accorded the benefit of the filing date of application 07/999,999, filed January 22, 1993 or (b) Jones moves for judgment against Smith on the ground that Smith's claims 1, 2 and 5 corresponding to the count are unpatentable under 35 U.S.C. § 103 over the combined

²³ The purpose of these requirements is to facilitate consideration of motions, to minimize the chance that an argument will be overlooked and to make it easier to determine whether a reply raises new issues.

disclosures of U.S. Patent No. 4,444,444
(Johnson) and French Patent 1,111,111
(Boleau)).

- (2) The evidence (i.e., a list of all exhibits by number) the moving party relies in support of the motion.
- (3) The facts in separately numbered paragraphs with a citation to the evidence.²⁴
- (4) An argument setting out the reasons why relief should be granted.

Oppositions

b. In presenting an opposition, a party shall set out in the following order:

- (1) The evidence (i.e., a list of all exhibits by number) the opposing party relies in support of the opposition.
- (2) Whether each fact alleged by the moving party is admitted, denied or that the opposing party is unable to admit or deny the fact alleged.
- (3) Any additional facts upon which the opposing party intends to rely with a citation to the evidence.

²⁴ A motion may be denied if the facts alleged are insufficient to state a claim for which relief may be granted. Facts belatedly set out only in the argument portion of a motion may be overlooked and may result in a motion being denied.

- (4) An argument stating the reason why relief is opposed shall be made in the following manner: "On page x, lines y-z of the motion, it is argued that _____. The response is _____."

Replies

c. In presenting a reply, a party shall set out in the following order:

- (1) The evidence relied upon (i.e., a list of all exhibits by number) by the replying party in support of the reply.
- (2) Whether each additional fact alleged by the opposing party is admitted, denied or that the moving party is unable to admit or deny the fact alleged.
- (3) Any additional facts upon which the moving party intends to rely to rebut additional facts alleged by the opposing party with a citation to the evidence and an explanation as to why each additional fact was not set out in the motion.
- (4) The argument responsive to statements in the opposition shall be made in the following manner: "On page x, lines y-z of the opposition, it is argued that _____. The response is _____."

Preliminary motion--anticipation

d. When anticipation (35 U.S.C. § 102) over a single prior art reference is the basis for a preliminary motion for judgment (37 CFR § 1.633(a)), each claim alleged to be anticipated should be reproduced as an appendix to the preliminary motion. Following each element recited in each claim, and within braces { }²⁵ and in bold, there shall be inserted a specific reference to the column and line and/or drawing figure and numeral and/or other material where the reference describes each element of the claim. A similar procedure should be used for each claim of an opponent which a party maintains is anticipated.

Preliminary motion--obviousness

e. When obviousness (i.e., 35 U.S.C. § 103) over the prior art is the basis for a preliminary motion for judgment (37 CFR § 1.633(a)), a similar procedure shall be used [at least one element or step recited in the claim will not be described in each prior art reference]. Any difference shall be explicitly identified. Finally, an explanation should be made as to why the subject matter of the claim, as a whole, would have been obvious to a person having ordinary skill in the art notwithstanding any difference. A similar procedure should be used for each claim of an opponent which a party maintains is unpatentable based on obviousness.

²⁵ Braces { } are required instead of brackets [] because brackets are used in claims in reissue applications.

Preliminary motion--request for testimony

f. If in connection with a preliminary motion (37 CFR § 1.633), a request is made for leave to take testimony to support the preliminary motion (37 CFR § 1.639), the request shall be made in the form of a miscellaneous motion (37 CFR § 1.635) separate from, and filed simultaneous with, the preliminary motion. A request to take testimony to support a preliminary motion may also be filed prior to the date preliminary motions are due. The procedures applicable to miscellaneous motions shall apply to any request for leave to take testimony to support the motion. See, inter alia, Paragraphs 23, 26-28 and 32 of the NOTICE DECLARING INTERFERENCE (Paper 1).

Preliminary Motion--inequitable conduct or fraud

g. The requirements of Paragraph 32 of this NOTICE DECLARING INTERFERENCE are applicable to any preliminary motion for judgment (37 CFR § 1.633(a)) based on inequitable conduct and/or fraud.

Motion to correct inventorship

h. A motion to correct inventorship (37 CFR § 1.634) may be filed at any time provided prior to filing the motion a conference call is placed by the moving party to the administrative patent judge. Time for filing the motion, opposition and reply will be set by the administrative patent judge. If necessary, appropriate action will be taken to

minimize prejudice to a non-moving party in those cases where the motion is to be filed after the time for filing preliminary motions.

27. Order accompanying motions²⁶

Each motion and opposition shall be accompanied by **two (2) copies** of a proposed order suitable for entry by the administrative patent judge. The form of the order should be as follows: "Upon consideration of Jones Miscellaneous Motion 4 and Smith opposition 4 thereto, it is ordered that the motion is granted (or denied)."

The last page of the proposed order shall contain a list of the counsel, their addresses and facsimile numbers to which the order shall be sent.

28. Page number limitation on motions, oppositions and replies

A motion is limited to twenty-five (25) pages, not including any certificate of service.

An opposition to a motion is limited to twenty-five (25) pages, not including any certificate of service.

A reply to an opposition is limited to ten (10) pages, not including any certificate of service.

²⁶ The purpose of this requirement is to permit motions to be decided and forwarded to the parties as promptly as possible, particularly those which do not require an opinion.

29. Use of double space typing

All typing in papers (including quotes and footnotes, but excluding headings, signature blocks and certificates of service) shall be double spaced. The use of footnotes is discouraged.

30. "Combined" oppositions and replies not to be filed²⁷

An opposition shall respond to only a single motion; "combined" oppositions responding to more than one motion shall not be filed.

A reply shall respond to only a single opposition; "combined" replies to more than one opposition shall not be filed.

31. No new issues to be raised in replies

As provided by the rules, no new issues are to be raised in replies.

A new issue will be deemed to be raised in a reply if the reply refers to new evidence which is necessary to make out a prima facie case for the relief requested in, and/or which could have been included with, the motion.

A reply which is longer than a motion or an opposition probably raises new issues.

If a reply raises any new issue or belatedly relies upon evidence which should have been earlier presented, **the entire reply and belatedly relied upon evidence will not be considered.**

²⁷ The purpose of this requirement is to minimize the possibility that an argument will be overlooked.

The board will not attempt to sort out legitimate reply from improper reply.²⁸

**32. Conference call prior to filing contested
Rule 635 motion**

Prior to filing a miscellaneous motion under 37 CFR § 1.635, a party shall:

- a. confer with all opponents as required by 37 CFR § 1.637(b) and, if agreement cannot be reached,
- b. place a conference call to the administrative patent judge designated to handle this interference.

A motion for a clarification of the procedure to be used in this interference shall not be filed until a conference call has been placed to the administrative patent judge designated to handle this interference.

The parties, at their expense, may--and are encouraged to--retain the services of a court reporter to record the telephone conference call. A court reporter is often desirable inasmuch as an oral decision may be made with respect to issues raised during the conference call.

33. Time for objection to admissibility of evidence

Any objection to the admissibility of evidence, including evidence filed with any motion, preliminary motion, opposition or

²⁸ The reason for this practice is to make the administration of justice in interferences more efficient by avoiding a need to sort out proper reply argument from improper reply argument.

reply shall be served (but not need not be filed) within **five (5) working days** of service of the evidence to which the objection is made. See Paragraph 48(a) for when the objection must be filed.

34. Time for serving supplemental affidavits

Any supplemental affidavit to respond to any objection to the admissibility of evidence shall be served (but not filed) within **two (2) weeks** of the date an objection was served.

35. Time for cross-examination

Unless otherwise agreed by the parties, cross-examination of any affiant may begin no earlier than **twenty-one (21) days**²⁹ after service of an affidavit.

A notice requesting cross-examination shall be served (and need not be filed).

Unless agreed to by the party requesting cross-examination, cross-examination of an affiant relied upon in a preliminary motion shall take place at least ten (10) days before an opposition to the preliminary motion is due.

Unless agreed to by the party requesting cross-examination, cross-examination of an affiant relied upon in an opposition to a preliminary motion shall take place at least ten (10) days before a reply is due.

²⁹ The twenty-one (21) day period is sufficient to allow for objections to the admissibility of evidence and the filing of supplemental affidavits.

36. Order and place of cross-examination

The party asking for cross-examination, upon reasonable notice, shall have the right to select the order in which cross-examination occurs when more than one witness is to be cross-examined.

Cross-examination shall take place at a reasonable location within the United States. Upon failure of the parties to agree, a conference call shall be placed to the administrative patent judge.

37. Reliance on a paper in a patent or application file

The specification and drawings of any involved or benefit application are evidence in an interference. 37 CFR § 1.671(a). Nevertheless, if a motion relies on a paper in the file of an involved or benefit patent and/or application (including a specification and/or drawings) involved in the interference, a copy of the paper shall be made an exhibit in the interference.

38. Affidavits in file wrappers not evidence

Affidavits, such as Rule 131 and Rule 132 affidavits, presented during ex parte prosecution of an involved and benefit application or patent are not evidence in an interference. If a party seeks to have such an affidavit considered, the party must place the affidavit in evidence as an exhibit. Any opponent will have an opportunity to object to the admissibility of the evidence and to cross-examine. A party submitting the evidence

will have an opportunity to supplement the evidence following a timely objection by an opponent.

39. Manner of labelling exhibits³⁰

Exhibits used by a party in this interference shall be assigned consecutive numbers throughout the course of the interference.

Exhibits should be identified by an exhibit number (not letters) on a label placed in the lower right-hand corner of the first page of the exhibit. Compare 37 CFR § 1.653(i).

If important material is covered by an exhibit label on the first page of the exhibit, a copy of the first page of the exhibit may be reproduced and presented as page 1-a of the exhibit.

Exhibits should be labeled, e.g., as follows:

Jones EXHIBIT 2001
Jones v. Smith
Interference 108,111

Smith EXHIBIT 1001
Jones v. Smith
Interference 108,111

Affidavits relied upon during the course of the interference shall be assigned an exhibit number.

The party currently designated as senior party shall consecutively number exhibits beginning with Exhibit 1001.

³⁰ The purpose of this requirement is to maximize the chance that any misplaced exhibit can be associated with the proper interference and to facilitate identification during deliberations as to who filed an exhibit.

The party currently designated as junior party shall consecutively number exhibits beginning with Exhibit 2001.³¹

At the conclusion of the preliminary motion period and at the time the record on the issue of priority is filed, the parties should plan on submitting all original exhibits, including affidavits, in an accordion folder, box or other folder containing all exhibits in numerical order, the idea being that each motion, opposition, reply, affidavit or transcript of cross-examination shall refer to the exhibit by number.

The filing of multiple copies of the same exhibit with different exhibit numbers is not authorized.

40. Exhibit list

Each party shall maintain an exhibit list. The list shall contain the exhibit number and a brief description thereof. Upon request by the board, the party should be prepared to file a copy of the exhibit list.

41. Specification as evidence

A specification of an application or patent involved in the interference is admissible as evidence only to prove what the specification or patent describes. If there is data in the specification upon which a party intends to rely to prove the truth of the data, an affidavit by an individual having first-hand knowledge of how the data was generated (i.e., the

³¹ Exhibits in a series above 2000 (i.e., 3000, 4000, etc.) are reserved for those interferences where there is more than one junior party.

individual who performed an experiment reported as an example in the specification) must be filed.

The individual will be subject to cross-examination.

42. Affidavits of expert witnesses

Affidavits expressing an opinion of an expert must disclose the underlying facts or data upon which the opinion is based.

See Fed. R. Evid. 705 and 37 CFR §§ 1.639(b) and 1.671(b).

Opinions expressed without disclosing the underlying facts or data may be given little, or no, weight. See Rohm and Haas Co. v. Brotech Corp., 127 F.3d 1089, 1092, 44 USPQ2d 1459, 1462 (Fed. Cir. 1997) (nothing in the Federal Rules of Evidence or Federal Circuit jurisprudence requires the fact finder to credit the unsupported assertions of an expert witness).

43. Reliance on scientific tests and data

Parties often rely on scientific tests and data, both in the preliminary motion phase and during the priority testimony phase. Examples include IR (infra-red spectroscopy) and graphs generated therefrom, HPLC (high performance liquid chromatography) and data generated therefrom, etc. In the event a party relies on a scientific test or data generated from a scientific test, the party relying on the test or data shall explain:

- a. the reason why the test is being used and why the data is being relied upon;
- b. how the test is performed;
- c. how the data is generated using the test;

- d. how the data is used to determine a value;
- e. the acknowledged accuracy of the test; and
- f. any other information which the party believes ;

would aid the board in understanding the significance of the test and/or data.

The explanation desirably takes place through an affidavit testimony of a witness, preferably accompanied by references to relevant pages of standard texts (which should be exhibits in the interference).

44. Letters between counsel not to be filed

Unless a letter between counsel is made an exhibit to a motion, opposition, reply, affidavit or during cross-examination, no letters between counsel are to be filed with the board.

45. Requirement for settlement negotiations³²

The parties are encouraged to attempt to settle this interference. Accordingly, within **three (3) months** of the date of this NOTICE DECLARING INTERFERENCE, the parties are required to conduct a settlement conference and discuss settlement possibilities. The senior party shall be responsible for initiating any settlement discussions. The administrative patent judge designated to handle this interference may be contacted via

³² The purpose of this paragraph is to facilitate settlement discussions. To eliminate any possibility that initiation of settlement discussions might be construed as a weakness on the party initiating settlement discussions, the senior party shall be responsible for initiating any settlement discussions, for initially drafting any document or for initiating any conference call required by this paragraph. The parties may agree to permit a junior party to undertake the obligation placed upon the senior party by this Paragraph.

telephone conference call to render any assistance which might accomplish settlement.

Within **three (3) months** of the date of this NOTICE DECLARING INTERFERENCE, the parties are required to initiate a telephone conference call with the administrative patent judge designated to handle this interference and should be prepared to discuss at that time:

- a. report on the outcome of the settlement conference;
- b. whether the parties are actively engaged in settlement negotiations and, if so, what steps have already been taken toward settlement;
- c. whether any settlement negotiations are directed toward resolving prior inventorship and obviating the need for filing preliminary motions;
- d. identify any issues which are not subject to settlement negotiations; and
- e. the status of any settlement negotiations, including how much time might be needed to conclude those negotiations.

Unless a different time is set in an order establishing a testimony period, within **two (2) months** after a decision on preliminary motions, the parties are further required to conduct a settlement conference and discuss settlement possibilities. Within the same time period, the parties are also required to initiate another telephone conference call with the

administrative patent judge designated to handle this interference and should be prepared to discuss at that time the items set out in paragraph a through e, supra.

Unless a different time is set in an order establishing a testimony period, within **one (1) month** after service of the record, the parties are still further required to conduct a settlement conference and discuss settlement possibilities. Within the same time period, the parties also are required to initiate another telephone conference call with the administrative patent judge designated to handle this interference and should be prepared to discuss at that time the items set out in paragraph a through e, supra.

Prior to initiating any conference call required by this paragraph, the parties are required to file (preferably by facsimile) a joint statement indicating that a good faith effort has been made to settle this interference.

46. Guidelines for cross-examination

Cross-examination is a useful tool for determining the facts in a case. In interference cases, testimony is initially presented by affidavit. 37 CFR § 1.639(b); 37 CFR § 1.672(b) and (c). Cross-examination occurs by oral deposition. 37 CFR § 1.672(d). With respect to the cross-examination depositions, the guidelines of Hon. Robert S. Gawthrop, III, U.S. District Judge, essentially as set out in his opinion in Hall v. Clifton Precision, a division of Litton Systems, Inc., 150 F.R.D. 525 (E.D. Pa. 1993), shall apply as hereinafter discussed. There is

only one basic exception and that exception is due to PTO rules. Objections must be noted on the record. See 37 CFR § 1.675(c).

As Judge Gawthrop notes, a deposition is meant to be a question-and-answer conversation between the deposing lawyer and the witness. There is no proper need for the witness's own lawyer to act as an intermediary, interpreting questions, deciding which questions the witness should answer, and helping the witness to formulate answers. The witness comes to the deposition to be questioned on cross-examination. It is the witness, and not the lawyer, who is the witness.

In view of the above, and pursuant to 37 CFR § 1.610(e), the following guidelines shall apply.

Guideline [1]

At the beginning of the deposition, deposing counsel taking cross-examination shall instruct the witness on the record to ask deposing counsel, rather than the witness's own counsel, for clarifications, definitions or explanations of any words, questions or documents presented during the course of the deposition. The witness shall abide by the instructions.

Guideline [2]

Counsel shall not direct or request that a witness not answer a question, unless:

(1) counsel has objected to the question on the ground that the answer would:

(a) reveal privileged material or

(b) violate a limitation imposed by an administrative patent judge or a panel of the Board of Patent Appeals and Interferences and

(2) counsel immediately places a telephone conference call to the administrative patent judge designated to handle this interference asking orally for a ruling on the objection.

Under these circumstances, (1) the deposition shall be suspended, (2) the telephone conference call immediately shall be placed to the administrative patent judge designated to handle this interference, and (3) all counsel must be prepared to address orally their respective positions. The court reporter in attendance at the deposition shall be available to record any telephone discussion and to read back questions to which an objection has been made.

If an administrative patent judge cannot be reached, then the party directing a witness not to answer shall, within **two (2) working days**, hand deliver to the Board (Crystal Gateway 2, 10th Floor, 1225 Jefferson Davis Highway, Arlington, Virginia), and not to the PTO Mail Room or any other PTO office, a motion under 37 CFR § 1.635 seeking relief. Any opposition must be hand delivered to the Board within **two (2) working days**. While a reply can be filed, counsel should assume that the motion is under advisement and can be decided at any time upon (a) receipt of an opposition, or (b) failing timely hand delivery of an opposition, then immediately.

Guideline [3]

Counsel shall not make objections or statements which might suggest an answer to a witness. Any objection to evidence during a deposition shall be stated concisely and in a non-argumentative and non-suggestive manner. Opposing counsel should not address the correctness of an objection. Rather, opposing counsel should continue with questions to the witness, the objection having been noted on the record as required by 37 CFR § 1.675(c).

With respect to this guideline, the following observation by Judge Gawthrop should be noted:

I also note that a favorite objection or interjection of lawyers is, "I don't understand the question; therefore the witness doesn't understand the question." This is not a proper objection. If the witness needs clarification, the witness may ask the deposing lawyer for clarification. A lawyer's purported lack of understanding is not a proper reason to interrupt a deposition. In addition, counsel are not permitted to state on the record their interpretations of questions, since those interpretations are irrelevant and often suggestive of a particularly desired answer.

By way of example, the following comments by counsel not conducting cross-examination generally are viewed as suggesting an answer to a witness:

1. Objection, vague.

2. Objection, to the form of the question.
3. Take your time in answering the question.
4. Look at the document before you answer.
5. Counsel, do you want to show him/her the document?

Guideline [4]

Counsel and their witness-clients shall not engage in private, off-the-record conferences during depositions or during breaks or recesses, except for the purpose of deciding whether to assert a privilege. The term "witness-clients" in the context of this guideline and patent interference practice includes all witnesses who are employed by, or otherwise under the control of, the real party in interest in the interference, including retained expert witnesses, as well as the individual or individuals named in the caption of the interference.

With respect to this guideline, the following observation by Judge Gawthrop should be noted:

The fact that there is no [administrative patent] judge in the room to prevent private conferences does not mean that such conferences should or may occur. The underlying reason for preventing private conferences is still present: they tend, at the very least, to give the appearance of obstructing the truth.

Guideline [5]

Any conferences which occur pursuant to, or in violation of, guideline [4] are a proper subject for inquiry by deposing

counsel to ascertain whether there has been any witness-coaching and, if so, what.

Guideline [6]

Any conferences which occur pursuant to, or in violation of, guideline [4] shall be noted on the record by the counsel who participated in the conference. The purpose and outcome of the conference shall also be noted on the record.

Guideline [7]

Deposing counsel taking cross-examination shall provide to the witness's counsel a copy of all documents shown to the witness during the deposition. The copies shall be provided either before the deposition begins or contemporaneously with the showing of each document to the witness. The witness and the witness's counsel do not have a right to discuss documents privately before the witness answers questions about the documents.

Failure to adhere strictly to these guidelines may be a basis for a sanction under 37 CFR § 1.616, which could include a requirement that the witness, on very short notice (i.e., the next day including if appropriate a non-work day) may be directed to appear before the board in Arlington, Virginia or elsewhere as may be appropriate, coupled with any appropriate award of compensatory damages under Rule 616. In addition, cross-examination undertaken contrary to these guidelines may result in exclusion of an affidavit from evidence or little, if any weight,

being given to the direct testimony of a witness who was cross-examined.

47. Comments on requests for extensions of time

The parties are advised that times have been set with the view to rendering prompt and timely decisions. Thus, in setting times in this interference, also taken into account are times set in other interference and decisions which need to be rendered in this interference, as well as other interference.

It is true that requests for extension of time are authorized by 37 CFR § 1.645. But, Rule 645 requires a showing of "good cause." Whatever counsel's experience may be in other PTO matters, prior interferences or courts generally, the standard of what constitutes "good cause" within the meaning of Rule 645 is considerably high.

There are few, if any, circumstances where "good cause" can be based on the press of other business arising after a time is set by an order entered in this interference, particularly where a time period is set after conference with counsel. Thus, a matter in another case (i.e., argument or a trial) or an event (i.e., a deposition, client meeting in the U.S. or abroad) scheduled or ordered after a conference call setting times in this interference, generally will not constitute grounds for an extension of time.

Generally, an attempt to settle is not "good cause." While settlement is encouraged, and the administrative patent judge designated to handle this interference is available to assist in

settlement efforts where appropriate, the parties should expect to either settle interference or, in the absence of settlement, to meet the next pending deadline.

48. Paper which is required to be served, but which need not be filed with the board³³

The following papers, which must be served on an opponent, need not be filed with the board at the time of service, but may need to be filed at a future date if a dispute arises with respect to the paper served:

a. An objection to the admissibility of evidence after service of an affidavit, exhibit or other evidence (the objection should be filed only as an attachment to a motion to suppress (37 CFR § 1.656(h))).

b. A notice requesting cross-examination.

49. Published precedent of the Trial Section

Published opinions entered by the Trial Section and other information which may be useful relating to interferences is available on the PTO Web Page at:

<http://www.uspto.gov/web/offices/dcom/bpai/its.htm>.

The web page is updated from time to time.

50. Testimony in a language other than English

A conference call shall be placed to the administrative patent judge designated to handle the interference **at least five**

³³ The purpose of the practice set out in this Paragraph is to eliminate filing of papers with the board which are intended to serve principally as notice to an opponent.

(5) **business days** before testimony is to take place when the witness will give direct or cross-examination testimony during a deposition in a foreign language. The conference call shall be ; initiated by the party who called the witness.

mck

FRED E. McKELVEY
Senior Administrative Patent Judge

5 April 2000
Arlington, VA

Attachment
(37 CFR § 1.611(c))

The parties involved in this interference are:

Junior Party

Named inventors: Alfred C. Nichols, Florence, AL
K. Lemone Yielding, Tuscombia, AL

Patent: U.S. Patent 5,783,700,
granted 21 July 1998,
based on application 08/887,627,
filed 3 July 1997

Title: Quinolic acid derivatives

Assignee: None

Attorneys: See last page

Accorded Benefit: None

Address: See last page

Senior Party

Named Inventors: Boris Tabakoff, Elizabeth, IL
Lawrence Snell, Aurora, CO
Paula L. Hoffman, Denver, CO

Application: Application 09/171,697,
filed 23 October 1998

Title: Compounds, compositions and method suitable
for amelioration of withdrawal syndromes and
withdrawal-induced brain damage

Assignee: None

Attorneys: See last page

Accorded Benefit: Provisional application 60/048,848,
filed 6 June 1997

Address: See last page

Count 1

A compound according to any of claim 1 or 15 of Nichols

or

a compound according to claim 12 of Tabakoff.

The claims of the parties are:

Nichols: 1-15

Tabakoff: 11-19 and 21-23

The claims of the parties which correspond to Count 1 are:

Nichols: 1-15

Tabakoff: 11-15 and 18-19

The claims of the parties which do not correspond to Count 1
are:

Nichols: None

Tabakoff: 16-17 and 21-23

Appendix

Paper No. _____

Filed on behalf of: Party _____
By: Name of lead counsel, Esq.
Name of backup counsel, Esq.
Street address
City, State, and Zip-Code
Tel:
Fax:

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES
(Senior Administrative Patent Judge Fred E. McKelvey)

ALFRED C. NICHOLS and K. LEMONE YIELDING,

Junior Party,
(Patent 5,783,700),

v.

BORIS TABAKOFF, LAWRENCE SNELL
and PAULA L. HOFFMAN,

Senior Party
(Application 09/171,697).

Patent Interference No. 104,522

TITLE OF PAPER

A. Summary of dates for taking action

Dates and times for taking action set in this NOTICE DECLARING INTERFERENCE are set out in **bold**. The following dates have been set in this NOTICE DECLARING INTERFERENCE:

1. **Paragraph 7:** date for identifying lead and backup counsel.
2. **Paragraph 8:** date for identifying any real party in interest.
3. **Paragraph 9:** date for requesting copies of involved and benefit applications and patents.
4. **Paragraph 17:** date and time for conference call.
5. **Paragraph 17:** date for filing list of preliminary motions to be filed.
6. **Paragraph 19:** date for accomplishing certain discovery.
7. **Paragraph 20:** date for filing clean copy of claims.
8. **Paragraph 21:** date for filing clean copy of claims in cases with drawings and/or claims containing a means plus function limitation.
9. **Paragraph 23:** dates for filing oppositions to Rule 635 motions and dates for filing replies to oppositions.
10. **Paragraph 33:** date for objecting to admissibility of evidence.
11. **Paragraph 34:** date for serving supplemental affidavits or evidence to respond to objection to admissibility of evidence.
12. **Paragraph 35:** date when cross-examination can take place.
13. **Paragraph 45:** dates for taking action with respect to settlement discussions

104,522
cc (via Federal Express):

Attorney for Nichols:

VEAL & ASSOCIATES
Suite 125
200 Cahaba Park Circle
Birmingham, AL 35242

Tel: None
Fax: None
E-mail: None

Attorney for Tabakoff:

Talivaldis Cepuritis, Esq.
OLSON & HIERL
20 North Wacker Drive
36th Floor
Chicago, IL 60606

Tel: None
Fax: None
E-mail: None

Enc:

Copy of order used for setting times for taking action in
the preliminary motion phase of the interference

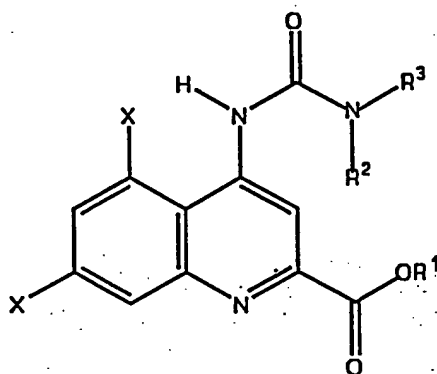
Copy of order used for setting times for taking action in
the testimony and briefing phases of the interference

PTO Form 850 (there is no Rule 609(b) statement)

DECLARE.006.1
Revised October 1999
(replaces DECLARE.005 and DECLARE.006)

withdrawal or withdrawal-induced brain damage manifested in a patient suffering withdrawal symptoms is disclosed. The term "withdrawal syndromes" as used herein includes, but is not limited to, manifestations of one or more symptoms of CNS hyperexcitability associated with alcohol withdrawal syndromes, neuroexcitability disorders associated with drug withdrawal syndromes, neural brain damage induced by alcohol or drug dependence withdrawal and like neurodegenerative disorders associated with chronic drug use and withdrawal.

A preferred method comprises administering a physiologically effective amount of a compound having the general formula (I):



(I)

a tautomer thereof, a pharmacologically acceptable ester, amide, salt, ether, or an acid addition salt thereof;

wherein R¹ represents hydrogen or an alkyl group of 1 to 6 carbon atoms;

R² and R³ each independently represent phenyl which may be unsubstituted or substituted one or more times with substituents selected from the group consisting of alkoxy, cycloalkoxy, alkyl, and cycloalkyl groups containing up to 6 carbon atoms, hydrogen, hydrocarbon selected from the group consisting of straight chain, branched, cyclic, and heterocyclic groups containing up to 18 carbon atoms, halogen, cyano, trifluoromethyl, nitro, -OR^a, -SR^a, -NR^aR^b, -NR^aCOR^b, -NR^aCO₂R^b, -NR^aSO₂R^b, -NRCZNR^aR^b, -CO₂, or -CONR^aR^b; wherein R^a, R^b, Rⁱ each independently represent hydrogen or hydrocarbon as described above and can be the same or different and Z represents oxygen,

sulphur, or a group of formula $=N,E$; wherein E represents hydrocarbon as described above or an electron-withdrawing group; or

5 R^2 and R^3 together with the intervening nitrogen and carbon atom represent carbonyl ($C=O$), thiocarbonyl ($C=S$), imino ($C=N,R^a$), oximino ($C=N,OR^a$), or a 3- to 8-membered ring containing from zero to 4 hetero-atoms selected from the group consisting of oxygen, nitrogen, sulphur and phosphorus; wherein R^a represents hydrogen or hydrocarbon as described above;

wherein each of the R^2 and R^3 substituents can be the same or different; and

10 X represents halogen and each of the 5, 7, substituents can be the same or different.

Administration of the compound can be by oral, intravenous, subcutaneous, intramuscular, intraperitoneal, transdermal or buccal means for therapeutic treatment.

15 Preferred compounds of the general formula (I) are N-substituted 4-ureido-5,7-dihalo-2-carboxy quinoline compounds. Particularly preferred compounds were derivatives of kynurenic acid, hereafter referred to generally as DCUK compounds. Presently preferred DCUK compounds are (N,N-diphenyl)-4-ureido-5,7-dichloro-2-carboxy-quinoline (DCUKA); (N,N-diphenyl)-4-ureido-20 5,7-dichloro-2-carboxy-quinoline methyl ester(DCUK-OMe); and N-phenyl, N-[2-methoxy]phenyl)-4-ureido-5,7-dichloro-2-carboxy-quinoline (MeO-DCUKA) which demonstrate affinity for both the strychnine-insensitive glycine binding site on the NMDA receptor complex and voltage-sensitive sodium channels.

25 The inventive DCUK compounds beneficially possess activity in reducing drug withdrawal-induced and excitotoxin-induced CNS hyperexcitability and neuronal damage at doses devoid of CNS depressant effects. Even at high doses, the DCUK compounds efficiently inhibit, in a use dependent manner, voltage sensitive sodium channels and inhibit NMDA receptor function without inducing the adverse marked behavioral stimulation and ataxia effects associated with known NMDA receptor antagonists or voltage sensitive sodium channel 30 blockers. Additionally, the inventive DCUK compounds beneficially reduce or prevent in vitro measures of glutamate excitotoxicity.

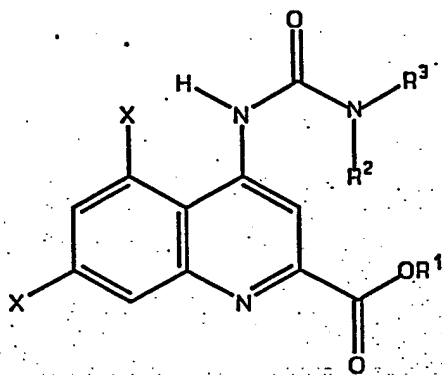
FIG. 13 shows the effects of (\pm)HA-966 on rotarod performance in naive C57BL/6 mice.

Detailed Description of Preferred Embodiment

5 Disclosed are compounds, compositions and a method suitable for treating dependence on, or preventing the withdrawal syndrome from being manifested during withdrawal from, the chronic use of ethanol, or other sedative or hypnotic or analgesic drugs in a patient (humans or other mammalian animal species). Withdrawal syndrome manifestations include, but are not limited to
10 CNS hyperexcitability, such as tremors, insomnia, anorexia, disorientation, seizures, convulsions, anxiety or the like. The present compounds, compositions and method also provide for treating neurodegenerative disorders associated with chronic drug use and withdrawal induced brain damage.

The method provided by the present invention comprises
15 administering by systemic means to a patient in need of such treatment or prevention an effective ameliorating amount of a compound which exhibits both an affinity for the strychnine-insensitive glycine binding site on the NMDA receptor complex and affinity for voltage-sensitive sodium channels (VSNAC).

A preferred compound embodiment has the general formula (I):



(I)

20

a tautomer thereof, a pharmacologically acceptable ester, amide, salt, ether, or an acid addition salt thereof;

wherein R^1 represents hydrogen or an alkyl group of 1 to 6 carbon atoms;

5 R^2 and R^3 each independently represent phenyl which may be unsubstituted or substituted one or more times with substituents selected from the group consisting of alkoxy, cycloalkoxy, alkyl, and cycloalkyl groups containing up to 6 carbon atoms, hydrogen, hydrocarbon selected from the group consisting of straight chain, branched, cyclic, and heterocyclic groups containing up to 18 carbon atoms, halogen, cyano, trifluoromethyl, nitro, $-OR^a$, $-SR^a$, $-NR^aR^b$, $-NR^aCOR^b$, $-NR^aCO_2R^b$, $-NR^aSO_2R^b$, $-NR^aCZNR^aR^b$, $-CO_2$, or $-CONR^aR^b$;
10 wherein R^a , R^b , R^i each independently represent hydrogen or hydrocarbon as described above and can be the same or different and Z represents oxygen, sulphur, or a group of formula $=N,E$; wherein E represents hydrocarbon as described above or an electron-withdrawing group; or

R^2 and R^3 together with the intervening nitrogen and carbon atom
15 represent carbonyl ($C=O$), thiocarbonyl ($C=S$), imino ($C=N,R^a$), oximino ($C=N,OR^a$), or a 3- to 8-membered ring containing from zero to 4 hetero-atoms selected from the group consisting of oxygen, nitrogen, sulphur and phosphorus; wherein R^a represents hydrogen or hydrocarbon as described above;

wherein each of the R^2 and R^3 substituents can be the same or
20 different; and

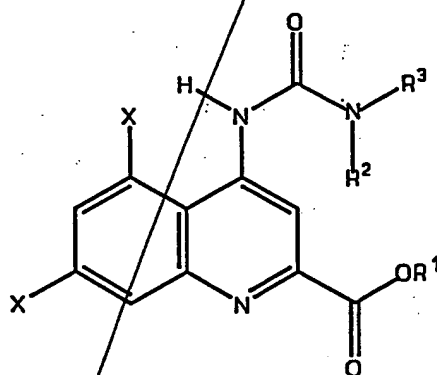
X represents halogen and each of the 5, 7, substituents can be the same or different.

The term "alkyl" as used herein refers to lower alkyl groups containing less than 7 carbon atoms. A preferred alkyl group has 1 to 3 carbon atoms. The term "hydrocarbon" as used herein includes straight-chained,
25 branched, and cyclic groups, including heterocyclic groups, containing up to 18 carbon atoms, suitably up to 15 carbon atoms, and conveniently up to 12 carbon atoms. The term "halogen" as used herein includes chloro, fluoro, bromo and iodo substituents, preferably chloro. The term "alkoxy" as used herein refers to
30 alkoxy groups containing less than 7 carbon atoms, preferably 1 to 3 carbon atoms. The term "substituted phenyl" refers to phenyl having one or more substituents selected from the group consisting of alkoxy, cycloalkoxy, alkyl, and

CLAIMS

WE CLAIM:

1. A method suitable for treating withdrawal syndromes manifested in a patient suffering withdrawal symptoms and/or withdrawal-induced brain damage which comprises administering an effective ameliorating amount of a compound having the general formula (I):



(I)

a tautomer thereof, a pharmacologically acceptable ester, amide, salt, ether, or an acid addition salt thereof;

wherein R¹ represents hydrogen or an alkyl group of 1 to 6 carbon atoms;

R² and R³ each independently represent phenyl which may be unsubstituted or substituted one or more times with substituents selected from the group consisting of alkoxy, cycloalkoxy, alkyl, and cycloalkyl groups containing up to 6 carbon atoms, hydrogen, hydrocarbon selected from the group consisting of straight chain, branched, cyclic, and heterocyclic groups containing up to 18 carbon atoms, halogen, cyano, trifluoromethyl, nitro, -OR^a, -SR^a, -NR^aR^b, -NR^aCOR^b, -NR^aCO₂R^b, -NR^aSO₂R^b, -NR^aCZNR^aR^b, -CO₂, or -CONR^aR^b;

wherein R^a, R^b, Rⁱ each independently represent hydrogen or hydrocarbon as described above and can be the same or different and Z represents oxygen, sulphur, or a group of formula =N,E; wherein E represents hydrocarbon as described above or an electron-withdrawing group; or

R² and R³ together with the intervening nitrogen and carbon atom represent carbonyl (C=O), thiocarbonyl (C=S), imino (C=N,R^a), oximino (C=N,OR^a), or a 3- to 8-membered ring containing from zero to 4 hetero-atoms

selected from the group consisting of oxygen, nitrogen, sulphur and phosphorus;
wherein R^a represents hydrogen or hydrocarbon as described above;

wherein each of the R^2 and R^3 substituents can be the same or
5 different; and

X represents halogen and each of the 5, 7, substituents can be the
same or different.

2. The method of claim 1 wherein in the compound of formula
(I) each of the X substituents is chloro, R^1 is hydrogen, and R^2 and R^3 each is a
10 phenyl group.

3. The method of claim 1 wherein in the compound of formula
(I) each of the X substituents is chloro, R^1 is an alkyl group having 1 to 3 carbon
atoms, and R^2 and R^3 each is a phenyl group.

4. The method of claim 1 wherein in the compound of formula
15 (I) each of the X substituents is chloro, R^1 is hydrogen, one of R^2 and R^3 is an
unsubstituted phenyl group and the other is phenyl having an alkoxy substituent
having 1 to 3 carbon atoms.

5. The method of claim 1 wherein the treatment is for alcohol
withdrawal.

20 6. The method of claim 1 wherein the treatment is for drug
withdrawal.

7. The method of claim 1 wherein the treatment is for
withdrawal-induced brain damage.

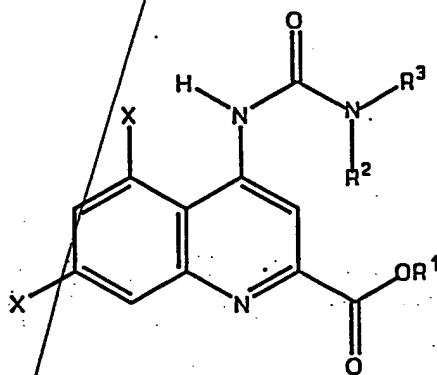
8. The method of claim 1 wherein the compound is
25 administered in an amount of up to about 500 mg/kg of body weight.

9. The method of claim 1 wherein the amount of compound
administered is in the range of about 10 to about 100 mg/kg of body weight.

10. A composition suitable for use in the method of claim 1
containing a compound selected from the group consisting of a compound of
30 formula (I), a tautomer, or pharmaceutically acceptable ester, amide, salt, ether
and addition salt thereof, in an amount of about 0.1 to about 95 weight percent
and a pharmaceutically acceptable vehicle.

11. The composition of claim 10 wherein the compound is selected from the group consisting of (N,N-diphenyl)-4-ureido-5,7-dichloro-2-carboxy-quinoline, (N,N-diphenyl)-4-ureido-5,7-dichloro-2-carboxy-quinoline methyl ester, and N-phenyl, N-[2-methoxy]phenyl)-4-ureido-5,7-dichloro-2-carboxy-quinoline.

12. A compound suitable for treating withdrawal syndromes manifested in a patient suffering withdrawal symptoms and/or withdrawal-induced brain damage which comprises administering an effective ameliorating amount of a compound having the general formula (I):



(I)

a tautomer thereof, a pharmacologically acceptable ester, amide, salt, ether, or an acid addition salt thereof;

wherein R¹ represents hydrogen or an alkyl group of 1 to 6 carbon atoms;

R² and R³ each independently represent phenyl which may be unsubstituted or substituted one or more times with substituents selected from the group consisting of alkoxy, cycloalkoxy, alkyl, and cycloalkyl groups containing up to 6 carbon atoms, hydrogen, hydrocarbon selected from the group consisting of straight chain, branched, cyclic, and heterocyclic groups containing up to 18 carbon atoms, halogen, cyano, trifluoromethyl, nitro, -OR^a, -SR^a, -NR^aR^b, -NR^aCOR^b, -NR^aCO₂R^b, -NR^aSO₂R^b, -NR^aCZNR^aR^b, -CO₂, or -CONR^aR^b; wherein R^a, R^b, Rⁱ each independently represent hydrogen or hydrocarbon as described above and can be the same or different and Z represents oxygen,

sulphur, or a group of formula $=N,E$; wherein E represents hydrocarbon as described above or an electron-withdrawing group; or

5 R^2 and R^3 together with the intervening nitrogen and carbon atom represent carbonyl ($C=O$), thiocarbonyl ($C=S$), imino ($C=N,R^a$), oximino ($C=N,OR^a$), or a 3- to 8-membered ring containing from zero to 4 hetero-atoms selected from the group consisting of oxygen, nitrogen, sulphur and phosphorus; wherein R^a represents hydrogen or hydrocarbon as described above;

wherein each of the R^2 and R^3 substituents can be the same or different; and

10 X represents halogen and each of the 5, 7, substituents can be the same or different.

13. A compound of claim 12 wherein each of the X substituents is chloro, R^1 is hydrogen, and R^2 and R^3 each is a phenyl group.

15 14. A compound of claim 12 wherein each of the X substituents is chloro, R^1 is an alkyl group having 1 to 3 carbon atoms, and R^2 and R^3 each is a phenyl group.

15 15. A compound of claim 12 wherein each of the X substituents is chloro, R^1 is hydrogen, one of R^2 and R^3 is an unsubstituted phenyl group and the other is phenyl having an alkoxy substituent having 1 to 3 carbon atoms.

20 16. A method of preparing a compound of claim 12 comprising the steps of:

a) reacting 3,5-dichloroaniline and dimethyl acetylenedicarboxylate to form dimethylanilinofumarate;

25 b) cyclizing the dimethylanilinofumarate with diphenyl ether to form 4(1H)-quinolone-2-carboxylate;

c) aminating the 4(1H)-quinolone-2-carboxylate with chlorosulphonyl isocyanate in acetonitrile to form a 4-aminated derivative thereof; and

30 d) acylating the 4-aminated derivative with diphenyl carbamoyl chloride to form (N,N-diphenyl)-4-ureido-5,7-dichloro-2-carboxy-quinoline methyl ester.